AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 - EXPEDITED PROCEDURE

Serial Number: 10/562,866 Filing Date: May 16, 2006

Title: Quil a fraction with low toxicity and use thereof

In the Claims

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Please amend the claims as follows.

1. (Currently amended) A method of enhancement of an immune response and immunomodulating activity comprising <u>intraperitoneally or subcutaneously administering</u> administration to a subject an effective amount of an adjuvant composition with synergistic effect comprising an iscom particle comprising

fraction A of Quil A together with at least one other adjuvant, wherein the at least one other adjuvant is in free form or integrated into another separate iscom particle other than the one in which the fraction A of Quil A was integrated.

- 2. (Previously Presented) The method according to claim 1 wherein said at least one other adjuvant is chosen from the group consisting of: saponins, naturally occurring saponin molecules derived from crude saponin extract of Quillaja saponaria Molina, synthetic saponin molecules derived from crude saponin extract of Quillaja saponaria Molina, semisynthetic saponin molecules derived from crude saponin extract of Quillaja saponaria Molin, saponin fractions from Quil A, saponin fractions from cell wall skeleton, blockpolymers, hydrophilic block copolymers, CRL-1005, Threhalose di mucolate (TDM), lipopeptides, LPS derivatives, LPS-derivatives, Lipid A from a bacterial species and derivatives thereof, monophosphoryl lipid A, CpG variants, CpGODN variants, endogenous human animal immunomodulators, GM-CSF. IL-2, native adjuvant active bacterial toxins, modified adjuvant active bacterial toxins, cholera toxin CT, CT subcomponent CTB, CT subcomponent CTA1, thermolabile toxin (LT) of E. coli, Bordetella pertussis (BP) toxin, and a filamentus heamagglutenin of BP.
- 3. (Previously Presented) The method according to claim 2 wherein the saponin fraction from Quil A is fraction C of Quil A or fraction B of Quil A.
- 4. (Previously Presented) The method according to claim 1, wherein said at least one other adjuvant is integrated into one iscom particle.

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5. (Previously Presented) The method according to claim 1, wherein said fraction A of Quil

A is integrated into a first iscom particle and said at least one other adjuvant is integrated into a

second iscom particle.

6. (Previously Presented) The method according to claim 5, wherein said at least one other

adjuvant is integrated into a plurality of separate iscom particles.

7. (Previously Presented) The method according to claim 4, wherein said fraction A of Quil

A is integrated into one iscom particle and said at least one other adjuvant is not integrated into

iscom particle.

8. (Previously Presented) The method according to claim 7, wherein said at least one other

adjuvant is at least one of monophosphoryl lipid A and cholera toxin CT.

9. (Previously Presented) The method according to claim 4, wherein said iscomparticle is

an iscom complex.

10. (Previously Presented) The method according to claim 4, wherein said iscom particle is

an iscom matrix complex.

11. (Previously Presented) The method according to claim 3, wherein the composition

comprises

50-99.9% of fragment A of Quil A; and

0.1-50% of a fraction or derivative of Quil A based on the total weight of the

composition.

12. (Previously Presented) The method according to claim 11, wherein the composition

comprises

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- 75-99.9% of fragment A of Quil A; and
- 0.1-25% of a fraction or derivative of Quil A based on the total weight of the composition.
- 13. (Previously Presented) The method according to claim 12, wherein the composition comprises
 - 91-99.1 % of fragment A of Quil A; and
 - 0.1-9% of a fraction or derivative of Quil A based on the total weight of the composition.
- 14. (Previously Presented) The method according to claim 1, wherein the composition further comprises a pharmaceutically acceptable carrier, diluent, excipient or additive.